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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,401	12/19/2005	Alex Abbas	P1998R1	2193
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GENENTECH, INC.			CHANDRA, GYAN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,401	Applicant(s) ABBAS ET AL.	
	Examiner Gyan Chandra	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, as drawn to an isolated nucleic acid having at least 80% identity with the nucleic acid that encodes a polypeptide of SEQ ID NO: 2, a vector comprising the same, a host cell comprising the vector and a process of producing a polypeptide of SEQ ID NO: 2.

Group 2, claim(s) 1-8, as drawn to an isolated nucleic acid having at least 80% identity with the nucleic acid that encodes a polypeptide of SEQ ID NOs 4,6.....207, 209, a vector comprising a nucleic acid of SEQ ID NOs: 3...206, 208, a host cell comprising the vector and a process of producing a polypeptide of SEQ ID NOs: 4,6.....207, 209.

Group 3, claim(s) 9-11, 14-17, in part, drawn to an isolated polypeptide having at least 80% amino acid sequence identity to an amino acid sequence of the SEQ ID NOs: 2, 4, 6...207 and 209, a chimeric molecule fused to a heterologous polypeptide, and a composition.

Group 4, claim(s) 12-17, as drawn to an antibody which specifically binds to an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209 and a kit comprising an antibody which specifically binds to an amino acid sequence of SEQ ID NOs: 2, 4, 6.....207 and 209.

Group 5, claim(s) 14-17, as drawn to a composition of an agonist of a polypeptide of SEQ ID NOs: 2, 4, 6.....207 and 209, and a kit comprising an agonist of a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 6, claim(s) 14-17, as drawn to a composition of an antagonist of a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, and a kit comprising an antagonist of a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209.

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Group 7, claim(s) 18-19, and 27 as drawn to a method of treating an immune related disorder in a mammal comprising administering a therapeutically effective amount of a polypeptide of an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209 or an agonist an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 8, claim(s) 18-19, as drawn to a method of treating an immune related disorder in a mammal comprising administering a therapeutically effective amount of an antagonist of an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209 or an antibody which binds to an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 9, claim(s) 20, drawn to a method of determining the presence of a polypeptide having an amino acid sequence of the SEQ ID NOs: 2, 4,6.....207 and 209 comprising an antibody which binds to a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 10, claim(s) 21 and 28, drawn to a method of diagnosing an immune related disease in a mammal comprising detecting the level of gene expression of a gene that encodes a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 11, claim(s) 22, drawn to a method of diagnosing an immune related disease in a mammal comprising detecting the formation of a complex between the antibody and a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 12, claim(s) 23, drawn to a method of identifying a compound that inhibits the activity of PRO polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 13, claim(s) 24-25, drawn to a method of identifying a compound that inhibits the expression of a gene encoding a PRO polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209.

Group 14, claim(s) 26, drawn to a method of identifying a compound that mimics the activity of a PRO polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209 comprising contacting cells which respond to said polypeptide with a candidate compound.

Groups 1-14 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group 1, requires the special technical feature of an isolated nucleic acid having at least 80% identity with the nucleic acid that encodes for a polypeptide of SEQ ID NO: 2, a vector comprising the same, a host cell comprising the vector and a process of producing a polypeptide of SEQ ID NO: 2. Sukhatme et al (US Patent No. 5206152 published on 4/27/1993) teach a nucleic acid of SEQ ID NO: 6 which is 91.6% (which is

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at least 80%) identical to the nucleic acid sequence of SEQ ID NO: 1 of the instant invention. Because the teachings of Sukhatme et al meet the limitation of a nucleic acid sequence at least 80% identical to the nucleic acid sequence of SEQ ID NO: 2, Sukhatme et al anticipates the instant invention. Therefore, Group 1 lacks a special technical feature and cannot share one with the other products of Groups 2-6.

Group 2, requires the special technical feature of an isolated nucleic acid having at least 80% identity with the nucleic acid that encodes a polypeptide of SEQ ID NOs 4, 6.....207, 209, or a vector comprising the same, a host cell comprising the vector and a process of producing a polypeptide of SEQ ID NOs: 4,6.....207, 209, which is not required for the products of Groups 1, 3-6.

Group 3, requires the special technical feature of an isolated polypeptide having at least 80% amino acid sequence identity to an amino acid sequence of the SEQ ID NOs: 2, 4, 6....207 and 209, a chimeric molecule fused to a heterologous polypeptide, and a composition, which is not required for the products of Groups 1, 2 and 4-6.

Group 4, requires the special technical feature of an antibody which specifically binds to an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209 and a kit comprising an antibody which specifically binds to an amino acid sequence of SEQ ID NOs: 2, 4, 6.....207 and 209, which is not required for the products of Groups 1-3, and 5-6.

Group 5, requires the special technical feature of a composition and a kit comprising an agonist of a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the products of Groups 1-4 and 6.

Group 6, requires the special technical feature of a composition and a kit comprising an antagonist of a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the products of Groups 1-5.

Group 7, requires the special technical feature of treating an immune related disorder in a mammal comprising administering a therapeutically effective amount of a polypeptide of an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209 or an agonist an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the methods of Groups 8-14.

Group 8, requires the special technical feature of treating an immune related disorder in a mammal comprising administering a therapeutically effective amount of an antagonist of an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209 or an antibody which binds to an amino acid sequence of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the methods of Groups 7 and 9-14.

Groups 9, requires the special technical feature of determining the presence of a polypeptide having an amino acid sequence of the SEQ ID NOs: 2, 4,6.....207 and 209

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comprising an antibody which binds to a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the methods of Groups 7-8 and 10-14.

Groups 10, requires the special technical feature of diagnosing an immune related disease in a mammal comprising detecting the level of gene expression of a gene that encodes a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the methods of Groups 7-9 and 11-14.

Groups 11, requires the special technical feature of diagnosing an immune related disease in a mammal comprising detecting the formation of a complex between the antibody and a polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the methods of Groups 7-10 and 12-14.

Groups 12, requires the special technical feature of identifying a compound that inhibits the activity of PRO polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the methods of Groups 7-11 and 13-14.

Groups 13, requires the special technical feature of identifying a compound that inhibits the expression of a gene encoding a PRO polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209, which is not required for the methods of Groups 7-12 and 14.

Groups 14, requires the special technical feature of identifying a compound that mimics the activity of a PRO polypeptide of SEQ ID NOs: 2, 4,6.....207 and 209 comprising contacting cells which respond to said polypeptide with a candidate compound., which is not required for the methods of Groups 7-13.

Further Restriction

Group 2

If Group 2 is elected, a further restriction to one of the following inventions is

required under 35 U.S.C. 121 or 372:

Nucleic Acids. The inventions of Group 2 are drawn to a number of nucleic acid

sequences (i.e., nucleic acid sequences that encodes the polypeptide

shown in Figure 1-209 which are SEQ ID NO: 3, 5,206 and 208).

Each of the claimed nucleic acid sequences are composed of different purine and pyrimidine units and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching two claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the

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non-coextensive nature of these searches. Therefore, Applicant must choose 1 sequence from the Nucleic Acids group against which the search should be performed.

Groups 3-14

Polypeptides: The inventions of Groups 3-14 as they pertain to the amino acid sequences (i.e., SEQ ID NO: 2, 4, 6 or 207 and 209).

Each of the claimed polypeptide sequences are composed of different amino acids and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching all of the above claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose 1 polypeptide sequence from the Polypeptide Group against which the search should be performed.

Species Election

This application contains claims directed to the following patentably distinct species:

Groups 7-8

Claim 19 is drawn to a number of patentably distinct species (immune related disorders) e.g., rheumatoid arthritis, osteoarthritis,.....splenomegaly and lekopenia.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species and that each species is different from other species in its structure and function relationship such as rheumatoid arthritis is very different than psoriasis or lekopenia. In addition, these species are not obvious variants of each other based on the current record.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and (ii) the species to be examined even though the requirement may be traversed (37 CFR 1.143) and (iii) identification of the claims encompassing the elected invention and the elected species.

The election of an invention and the species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention and species.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions or the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions or the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant elects a group from Group 7-8, one species from the immune related disorder group must be choose to be considered fully responsive. It noted that the election of a polypeptide or polynucleotide is restriction election and a species election.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1646
11 November 2007
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/Robert Landsman/
Primary Examiner, Art Unit 1647